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H. R. 830

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food from foreign countries.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 24, 1999

Mr. DINGELL (for himself, Mr. BROWN of Ohio, Mr. STUPAK, Mr. PALLONE, Mr. WAXMAN, Mr. MARKEY, Mr. BOUCHER, Mr. GORDON, Mr. DEUTSCH, Mr. RUSH, Mr. KLINK, Mr. WYNN, Mr. GREEN of Texas, Ms. MCCARTHY of Missouri, Ms. DEGETTE, Mr. BARRETT of Wisconsin, Mrs. CAPPS, Mr. BONIOR, and Mr. SERRANO) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food from foreign countries.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Imported Food Safety
5 Act of 1999”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1 (1) The Food and Drug Administration (FDA)
2 has confirmed that the number of produce-related
3 foodborne illness outbreaks in the United States has
4 increased in recent years.

5 (2) Imported food poses a special problem for
6 FDA in its efforts to guarantee the health and safe-
7 ty of the food American consumers eat. While FDA
8 has the ability to inspect and test food produced in
9 the United States at every stage of production, dis-
10 tribution, and sale, FDA may have access to im-
11 ported food for only a matter of hours at the inter-
12 national border, and it cannot trace back beyond the
13 border the origin of imported food believed to be re-
14 sponsible for outbreaks of foodborne illnesses.

15 (3) FDA data demonstrate that the pesticide
16 violation rate for imported food entering the United
17 States is nearly three time as great as for domesti-
18 cally produced food.

19 (4) FDA says its resources to deal with im-
20 ported food safety are limited. The General Account-
21 ing Office reported that between 1992 and 1997, the
22 number of imported food entries increased by more
23 than 200 percent, from 1.1 million to 2.7 million. At
24 the same time, FDA inspection of imported food has

1 fallen from an estimated 8 percent in fiscal year
2 1992 to 1.7 percent in fiscal year 1997.

3 (5) FDA confirms that there is a critical need
4 for rapid, accurate methods to detect, identify, and
5 quantify pathogens. For example, FDA can identify
6 only about half of the approximately 400 pesticides
7 for which the Environmental Protection Agency has
8 established tolerances. In addition, FDA says its
9 method for detecting hepatitis A on shellfish is inef-
10 fective for strawberries, and its method for detecting
11 cyclospora on raspberries is also ineffective.

12 (6) FDA lacks statutory authority to maintain
13 physical custody of imported foods until the admissi-
14 bility of the food has been determined, creating a
15 critical need for pathogen detection tests that will
16 produce real-time results while imported food is still
17 before FDA inspectors at the international border.

18 **SEC. 3. ADDITIONAL AUTHORITIES OF FOOD AND DRUG AD-**
19 **MINISTRATION REGARDING FOOD SAFETY.**

20 (a) REQUIREMENT FOR PRIOR APPROVAL OF SEC-
21 RETARY FOR COMMERCIAL DISTRIBUTION AND RELATED
22 ACTIVITIES.—Section 801 of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 381) is amended—

24 (1) by striking “(b) Pending decision” and in-
25 serting “(b)(1) Pending decision”, and by redesignig-

1 nating subsection (c) as paragraph (2) of subsection
2 (b); and

3 (2) by inserting after subsection (b) the follow-
4 ing subsection:

5 “(c)(1) Food entering the United States shall not,
6 without the prior approval of the Secretary, be—

7 “(A) transferred from the control of the person
8 who held control when the food entered the United
9 States;

10 “(B) commercially distributed within the
11 United States; or

12 “(C) removed from its intact state, with respect
13 to the manner in which the food was packed for
14 transport.

15 “(2) In determining whether to grant approval under
16 paragraph (1), the Secretary shall consider the following:

17 “(A) Whether the person or persons preparing,
18 packing, holding, manufacturing, or processing the
19 food involved cooperate with the Secretary in inspec-
20 tions regarding the food that are conducted by the
21 Secretary (including inspections conducted in foreign
22 countries).

23 “(B) Whether the person or persons have a his-
24 tory of failing to comply with applicable provisions
25 of this Act regarding food.

1 “(C) Whether the food (as a particular type of
2 product) has such a history.

3 “(D) Whether there is such a history with re-
4 spect to a particular foreign country.

5 “(E) Whether the system of regulating food
6 maintained in the foreign country provides at least
7 the same level of protection as domestic laws that
8 affect the safety of the food supply.

9 “(F) Whether the foreign country permits the
10 Secretary to conduct within the country inspections
11 regarding food.

12 “(G) Such other factors as the Secretary deter-
13 mines to be appropriate.

14 “(3)(A) If the system of regulating food maintained
15 in a foreign country does not provide at least the same
16 level of protection as domestic laws that affect the safety
17 of the food supply, or if the foreign country does not per-
18 mit the Secretary to conduct within the country inspec-
19 tions regarding food, the Secretary shall deny approval
20 under paragraph (1) for all food prepared, packed, held,
21 manufactured, or processed in the foreign country, except
22 as provided in subparagraph (B).

23 “(B) In the case of a foreign country with respect
24 to which approval under paragraph (1) has been denied
25 under subparagraph (A), a shipment of food prepared,

1 packed, held, manufactured, or processed in the foreign
2 country may be granted approval under such paragraph
3 if the Secretary receives proof satisfactory to the Secretary
4 that food in the shipment is not adulterated. The Sec-
5 retary shall require for purposes of the preceding sentence
6 that proof be presented that the shipment has been tested
7 for the presence of microbial pathogens and pesticide
8 chemicals or related residues, and for such other sub-
9 stances as the Secretary determines to be appropriate.

10 “(4) The Secretary shall by regulation provide for the
11 marking of any shipment of food that has been denied ap-
12 proval under paragraph (1) in a manner making it readily
13 apparent that the food has been refused admission into
14 the United States.

15 “(5) The Secretary shall give high priority to increas-
16 ing significantly, relative to fiscal year 1999, the number
17 of inspections under this section, including the testing of
18 imported food for pesticide and microbial contamination,
19 that are conducted with respect to food at ports of entry
20 into the United States.

21 “(6)(A) The Secretary shall submit to the Congress
22 periodic reports describing the activities of the Secretary
23 under this section with respect to the safety of food.

24 “(B) Each report under subparagraph (A) shall, for
25 each port of entry into the United States, specify the num-

ber of inspections and tests that were conducted under this section with respect to food during the preceding fiscal year, and the extent to which such number is an increase over the number of such inspections specified for such port in the preceding report under subparagraph (A).

“(C) Each report under subparagraph (A) shall state the statistical methodologies used by the Secretary in sampling food for purposes of inspections under this section, including the testing of imported food for pesticide and microbial contamination, and the levels of confidence associated with the methodologies.

“(D) The first report under subparagraph (A) shall be submitted not later than December 1, 2000, and subsequent reports shall be submitted annually thereafter.”.

(b) CRIMINAL PENALTIES.—

(1) ACTING WITHOUT APPROVAL OF SECRETARY.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

“(aa)(1) In the case of food, the carrying out of any act in violation of section 801(c)(1).”.

(2) FAILURE TO DISPOSE OF FOODS DENIED ENTRY.—Section 301(aa) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(aa)), as

1 added by paragraph (1), is amended by adding at
2 the end the following:

3 “(2) The failure to comply with an order under sec-
4 tion 801 regarding the disposition of food that for pur-
5 poses of such section has been refused admission or denied
6 the approval of the Secretary.”.

7 (3) FAILURE TO PROVIDE COUNTRY-OF-ORIGIN
8 LABELING FOR CERTAIN FOODS.—Section 403 of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 343) is amended by adding at the end the following:

11 “(t) If it is a food intended for human consumption,
12 it is grown, prepared, packed, manufactured, or processed
13 in a foreign country, and it fails, at the time the food is
14 offered for retail sale, to bear or be accompanied by label-
15 ing that identifies the country or countries in which the
16 food was grown, prepared, packed, manufactured, or proc-
17 essed, except that this paragraph does not apply to food
18 offered for retail sale by restaurants or other eating estab-
19 lishments.”.

20 (c) CONFORMING AMENDMENT.—Section 801 of the
21 Federal Food, Drug, and Cosmetic Act, as amended by
22 subsection (a), is amended in subsection (b)(2) by striking
23 “subsection (b)” and inserting “paragraph (1)”.

1 **SEC. 4. RESEARCH ON TESTING TECHNIQUES FOR USE IN**
2 **INSPECTIONS OF FOOD SAFETY.**

3 Section 801 of the Federal Food, Drug, and Cosmetic
4 Act, as amended by section 3(a), is amended in subsection
5 (c) by adding at the end the following paragraph:

6 “(7)(A) The Secretary shall (directly or through
7 grants or contracts) provide for research on the develop-
8 ment of tests and sampling methodologies, for use in in-
9 spections of food under this section—

10 “(i) whose purpose is to determine whether food
11 is adulterated by reason of being contaminated with
12 microorganisms or pesticide chemicals or related res-
13 idues; and

14 “(ii) whose results are available not later than
15 approximately 60 minutes after the administration
16 of the tests.

17 “(B) In providing for research under subparagraph
18 (A), the Secretary shall give priority to conducting re-
19 search on the development of tests that are suitable for
20 inspections of food at ports of entry into the United
21 States.

22 “(C)(i) In providing for research under subparagraph
23 (A), the Secretary shall under subparagraph (B) give pri-
24 ority to conducting research on the development of tests
25 for detecting the presence in food of the pathogens *E. coli*,
26 salmonella, cyclospora, cryptosporidium, hepatitis A, or

1 listeria, the presence in or on food of pesticide chemicals
2 and related residues, and the presence in or on food of
3 such other pathogens or substances as the Secretary deter-
4 mines to be appropriate. The Secretary shall establish the
5 goal of developing, by the expiration of the three-year pe-
6 riod beginning on the date of the enactment of the Im-
7 ported Food Safety Act of 1999, tests under subparagraph
8 (A) for each of the pathogens and substances receiving
9 priority under the preceding sentence.

10 “(ii) The Secretary shall submit to the Congress peri-
11 odic reports describing the progress that has been made
12 toward the goal referred to in clause (i) and describing
13 plans for future research toward the goal. Each of the re-
14 ports shall provide an estimate by the Secretary of the
15 amount of funds needed to meet such goal, and shall pro-
16 vide a determination by the Secretary of whether there
17 is a need for further research under this paragraph. The
18 first such report shall be submitted not later than March
19 1, 2000, and subsequent reports shall be submitted semi-
20 annually after the submission of the first report until the
21 goal is met.

22 “(D) The Secretary shall carry out the program of
23 research under subparagraph (A) in consultation with the
24 Director of the Centers for Disease Control and Preven-
25 tion, the Director of the National Institutes of Health, and

1 the Administrator of the Environmental Protection Agen-
 2 cy. The Secretary shall with respect to such research co-
 3 ordinate the activities of the Department of Health and
 4 Human Services. The Secretary shall in addition consult
 5 with the Secretary of Agriculture (acting through the
 6 Food Safety Inspection Service of the Department of Agri-
 7 culture) in carrying out the program.

8 “(E) Of the amounts reserved under section
 9 801A(a)(2)(B)(ii) for a fiscal year for carrying out the
 10 program of research under subparagraph (A), the Sec-
 11 retary shall make available not less than 50 percent for
 12 making awards of grants or contracts to private entities
 13 to conduct such research.”.

14 **SEC. 5. USER FEES REGARDING INSPECTIONS OF FOOD**
 15 **SAFETY.**

16 Chapter VIII of the Federal Food, Drug, and Cos-
 17 metic Act (21 U.S.C. 381 et seq.) is amended by inserting
 18 after section 801 the following section:

19 “USER FEES REGARDING FOOD SAFETY

20 “SEC. 801A. (a) IN GENERAL.—

21 “(1) ASSESSMENT.—Beginning in fiscal year
 22 2000, the Secretary shall in accordance with this
 23 section assess and collect fees on food imported into
 24 the United States.

25 “(2) PURPOSE OF FEES.—

1 “(A) IN GENERAL.—The purpose of fees
2 under paragraph (1) is to defray increases in
3 the costs of the resources allocated for carrying
4 out section 801 with respect to food over the
5 costs of carrying out such section with respect
6 to food in fiscal year 1999 multiplied by the ad-
7 justment factor. Increases referred to in the
8 preceding sentence include increases in such
9 costs for an additional number of full-time
10 equivalent positions in the Department of
11 Health and Human Services to be engaged in
12 carrying out such section.

13 “(B) ALLOCATIONS BY SECRETARY.—Of
14 the total fee revenues collected under paragraph
15 (1) for a fiscal year, the Secretary shall reserve
16 and expend amounts in accordance with the fol-
17 lowing:

18 “(i) The Secretary shall reserve not
19 less than 50 percent for carrying out sec-
20 tion 801 with respect to food, other than
21 research under subsection (c)(7) of such
22 section. In expending the amount so re-
23 served, the Secretary shall give priority to
24 inspections conducted at ports of entry
25 into the United States.

1 “(ii) The Secretary shall reserve not
2 more than 50 percent for carrying out re-
3 search under section 801(c)(7).

4 “(3) AMOUNT OF FEE; COLLECTION.—A fee
5 under paragraph (1) shall be assessed on each line
6 item of food, as defined by the Secretary by regula-
7 tion. The amount of the fee shall be based on the
8 number of line items, and may not exceed \$20 per
9 line item, notwithstanding subsection (b). The liabil-
10 ity for the fee constitutes a personal debt due to the
11 United States, and such liability accrues on the date
12 on which the Secretary approves the food under sec-
13 tion 801(c)(1). The Secretary may coordinate with
14 and seek the cooperation of other agencies of the
15 Federal Government regarding the collection of such
16 fees.

17 “(b) TOTAL FEE REVENUES.—The total fee revenues
18 collected under subsection (a) for a fiscal year shall be
19 the amount appropriated under subsection (f)(3).

20 “(c) ADJUSTMENTS.—

21 “(1) INFLATION ADJUSTMENT.—With respect
22 to the amount of total fee revenues referred to in
23 subsection (b), the amount authorized in subsection
24 (f)(3) for a fiscal year shall be adjusted by the Sec-

1 retary (and as adjusted shall be published in the
2 Federal Register) to reflect the greater of—

3 “(A) the total percentage change that oc-
4 curred during the preceding fiscal year in the
5 Consumer Price Index for all urban consumers
6 (all items; U.S. city average); or

7 “(B) the total percentage change for such
8 fiscal year in basic pay under the General
9 Schedule in accordance with section 5332 of
10 title 5, United States Code, as adjusted by any
11 locality-based comparability payment pursuant
12 to section 5304 of such title for Federal em-
13 ployees stationed in the District of Columbia.

14 “(2) ANNUAL FEE ADJUSTMENT.—Not later
15 than 60 days after the end of each fiscal year begin-
16 ning after fiscal year 2000, the Secretary, subject to
17 not exceeding the maximum fee amount specified in
18 subsection (a)(3), shall adjust the amounts that oth-
19 erwise would under subsection (a) be assessed as
20 fees during the fiscal year in which the adjustment
21 occurs so that the total revenues collected in such
22 fees for such fiscal year equal the amount applicable
23 pursuant to subsection (b) for the fiscal year.

24 “(d) FEE WAIVER OR REDUCTION.—The Secretary
25 shall grant a waiver from or a reduction of a fee assessed

1 under subsection (a) where the Secretary finds that the
2 fee to be paid will exceed the anticipated present and fu-
3 ture costs incurred by the Secretary in carrying out sec-
4 tion 801 with respect to food (which finding may be made
5 by the Secretary using standard costs).

6 “(e) ASSESSMENT OF FEES.—

7 “(1) LIMITATION.—Fees may not be assessed
8 under subsection (a) for a fiscal year beginning after
9 fiscal year 2000 unless the amount appropriated for
10 salaries and expenses of the Food and Drug Admin-
11 istration for such fiscal year is equal to or greater
12 than the amount appropriated for salaries and ex-
13 penses of the Food and Drug Administration for fis-
14 cal year 2000 multiplied by the adjustment factor
15 applicable to the fiscal year involved, except that in
16 making determinations under this paragraph for the
17 fiscal years involved there shall be excluded—

18 “(A) the amounts appropriated under sub-
19 section (f)(3) for the fiscal years involved; and

20 “(B) the amounts appropriated under sec-
21 tion 736(g) for such fiscal years.

22 “(2) AUTHORITY.—If the Secretary does not
23 assess fees under subsection (a) during any portion
24 of a fiscal year because of paragraph (1) and if at
25 a later date in such fiscal year the Secretary may as-

1 sess such fees, the Secretary may assess and collect
2 such fees, without any modification in the rate of
3 the fees, at any time in such fiscal year notwith-
4 standing the provisions of subsection (a)(3) relating
5 to the time at which fees are to be paid.

6 “(f) CREDITING AND AVAILABILITY OF FEES.—

7 “(1) IN GENERAL.—Fees collected for a fiscal
8 year pursuant to subsection (a) shall be credited to
9 the appropriation account for salaries and expenses
10 of the Food and Drug Administration and shall be
11 available in accordance with appropriation Acts until
12 expended without fiscal year limitation. Such sums
13 as may be necessary may be transferred from the
14 Food and Drug Administration salaries and ex-
15 penses appropriation account without fiscal year lim-
16 itation to such appropriation account for salaries
17 and expenses with such fiscal year limitation. The
18 sums transferred shall be available solely for carry-
19 ing out section 801 with respect to food, and the
20 sums are subject to allocations under subsection
21 (a)(2)(B).

22 “(2) COLLECTIONS AND APPROPRIATION
23 ACTS.—The fees authorized in subsection (a)—

1 “(A) shall be collected in each fiscal year
2 in accordance with subsections (a)(3) and (b);
3 and

4 “(B) shall only be collected and available
5 for the purpose specified in subsection (a)(2).

6 “(3) AUTHORIZATION OF APPROPRIATIONS; AL-
7 LOCATIONS BY SECRETARY.—Subject to paragraph
8 (4) and subsection (c)(1), there is authorized to be
9 appropriated for fees under this section \$56,000,000
10 for each of the fiscal years 2000 through 2004.

11 “(4) OFFSET.—Any amount of fees collected
12 for a fiscal year under subsection (a) that exceeds
13 the amount of fees specified in appropriation Acts
14 for such fiscal year shall be credited to the appro-
15 priation account of the Food and Drug Administra-
16 tion as provided in paragraph (1), and shall be sub-
17 tracted from the amount of fees that would other-
18 wise be authorized to be collected under this section
19 pursuant to appropriation Acts for a subsequent fis-
20 cal year.

21 “(g) COLLECTION OF UNPAID FEES.—In any case
22 where the Secretary does not receive payment of a fee as-
23 sessed under subsection (a) within 30 days after it is due,
24 such fee shall be treated as a claim of the United States

1 Government subject to subchapter II of chapter 37 of title
2 31, United States Code.

3 “(h) CONSTRUCTION.—This section may not be con-
4 strued as requiring that the number of full-time equivalent
5 positions in the Department of Health and Human Serv-
6 ices, for officers, employers, and advisory committees not
7 engaged in carrying out section 801 with respect to food
8 be reduced to offset the number of officers, employees, and
9 advisory committees so engaged.

10 “(i) DEFINITION OF ADJUSTMENT FACTOR.—For
11 purposes of this section, the term ‘adjustment factor’ ap-
12 plicable to a fiscal year is the lower of—

13 “(1) the Consumer Price Index for all urban
14 consumers (all items; United States city average) for
15 April of the preceding fiscal year divided by such
16 Index for April 1999; or

17 “(2) the total of discretionary budget authority
18 provided for programs in categories other than the
19 defense category for the immediately preceding fiscal
20 year (as reported in the Office of Management and
21 Budget sequestration preview report, if available, re-
22 quired under section 254(c) of the Balanced Budget
23 and Emergency Deficit Control Act of 1985) divided
24 by such budget authority for fiscal year 1999 (as re-
25 ported in the Office of Management and Budget

1 final sequestration report submitted after the end of
2 the 105th Congress, 2d Session).
3 The terms ‘budget authority’ and ‘category’ in subpara-
4 graph (B) are as defined in the Balanced Budget and
5 Emergency Deficit Control Act of 1985.”.

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